DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

95092d

October 27, 2004

05-DAL-WL-04

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ricky J. Baker, President/Owner
Rick's Gulf Tex Seafood, Inc.
P.O. Box 9136
Bacliff, Texas 77518

Dear Mr. Baker:

We inspected your firm, Rick's Gulf Tex Seafood, Inc., located at 826 25th Street, San Leon, Texas, 77539 on August 23-25, 27, 2004. Our inspection found that your firm has serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR §123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to otherwise operate in accordance with the requirements of 21 CFR Part 123 renders the processor's fishery products adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 342(a)(4). Accordingly, your fresh cooked crabmeat is adulterated, in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations that were found during the inspection were as follows:

1. Pursuant to 21 CFR §123.6(b), your firm must implement the monitoring procedures listed in your HACCP plan that must be met at each of the critical control points (CCPs) to ensure compliance with the critical limits (CLs).

   Although your firm's HACCP plan lists the monitoring procedure for the Receiving CCP CL as obtaining a signed letter from the supplier of live crabs to guarantee that the crabs were not harvested from a closed area or an area under consumption advisory, your firm's HACCP plan

has not been fully implemented with respect to monitoring this CL. Specifically, your firm is not receiving a signed letter from live crab fishermen for product received from Galveston Bay, Texas, and there is currently an advisory for the upper portion of Galveston Bay for the consumption of blue crabs. Your firm is receiving signed letters documenting the harvest areas of other bays.

Furthermore, your firm did not follow the monitoring procedure listed in your HACCP plan for recording the temperature at the time the crab backing and rinse step began. For example, on 8/24/2004, the time was recorded when the backed crabs were placed in the cooler, not when the actual backing and rinsing process began.

In addition, your firm did not monitor the temperature of the Backed Crab Cooler continuously from 8/14-15/2004, when cooked crab bodies were stored in this cooler; your firm has no temperature records for these dates. Also, there is no ice used on this product during storage to ensure proper refrigeration; therefore, the growth of pathogens in this ready-to-eat product may occur.

2. Pursuant to 21 CFR §123.6(c)(4), your firm must have a HACCP plan that lists the monitoring procedures and their frequency for each CCP. However, your firm's procedures/frequencies at the Cooking CCP does not meet the CL set for cooking and is not adequate to control the food safety hazard of pathogen growth.

   For example, your firm lists under the monitoring procedure for Cooking a temperature of [redacted] degrees Fahrenheit for [redacted] minutes; however, the CL sets the cook temperature at [redacted] degrees Fahrenheit for [redacted] minutes. In addition, under frequencies, the implementation of a continuous monitoring device is not listed on your HACCP plan for the cook. Therefore, your firm's monitoring procedures/frequencies are not sufficient in temperature, time, and continuous monitoring for the cooking of the crabmeat during processing to control pathogen growth.

3. Pursuant to 21 CFR §123.7(a), your firm must take a corrective action whenever a deviation from a CL occurs. However, your firm did not take any corrective action as set forth in your firm's HACCP plan when the cooking temperature only reached the internal temperature of [redacted] degrees Fahrenheit for [redacted] minutes during the second cook on 8/24/2004. Because the cooking temperature is recorded by a continuous monitoring device, this deviation was not noticed by management.

4. Pursuant to 21 CFR §123.11(b), your firm must monitor sanitation conditions and practices during processing with sufficient frequency to

ensure conformance with 21 CFR Part 110. However, your firm is not monitoring and maintaining sanitation conditions as they relate to Seafood HACCP to ensure conformance to 21 CFR Part 110. Your firm's Daily Sanitation Audit Form dated 8/24/2004 has the required items as P for "passed" in the "end of operation" column. This record does not contain the initials of the person completing the sanitation record.

The following specific conditions were observed by the investigator during this inspection:

Condition and Cleanliness of Food Contact Surfaces [21 CFR §123.11(b)(2)]:

- Crab cooking baskets have remains of cooked crabs from the previous day cooking operation. The baskets are not thoroughly washed, rinsed, and sanitized before and after the cooking process.

Prevention of Cross-Contamination from Insanitary Objects [21 CFR §123.11(b)(3)]:

- One employee from the cooking room is also responsible for the backing room operations. The employee's apron came into contact with the raw crabs in the cooking basket and then in contact with the cooked crabs in the backing room. The employee did not wash, rinse, and sanitize his apron after the direct contact with the raw crab in the cooking room.

- The backing room employees are wearing cotton gloves to pick the backs of the cooked crabs; therefore, the cotton gloves come into direct contact with the cooked product. Cotton gloves are not easily cleanable.

- Management took the internal temperature reading of cooked crabs with a thermometer that was not previously washed, rinsed, and sanitized. The crab body or claw was returned to the basket after the temperature of the product was evaluated.

- The gloves used by one employee to move the baskets of cooked crabs were found stored on the wet floor of the backing room. The employee had to be asked to wash, rinse, and sanitize the gloves prior to use and to store them in a more appropriate manner that would not lead to the cross-contamination of the cooked product.

Protection of Food from Adulteration with Lubricants, Cleaning Compounds, Sanitizing Agents, Condensate, and other Chemical, Physical and Biological Contaminants [21 CFR §123.11(b)(5)]:

- Condensation from an air conditioning unit was found dripping into a crab cooking basket. The crab cooking basket was being loaded with live blue crabs during the sorting and grading procedure. The condensate may contain chemical and biological contaminants.

5. Pursuant to 21 CFR §123.11(c), your firm must maintain sanitation control records that, at a minimum, document the monitoring and corrections to comply with 21 CFR §123.11(b). However, your firm did not maintain sanitation records for: safety of the water that comes into contact with food or food contact surfaces; proper labeling, storage, and use of toxic compounds; control of employee health conditions that could result in contamination; and exclusion of pests on the sanitation record for the backing room operation.

6. Pursuant to 21 CFR §123.6(c)(7), your firm's HAACP plan must provide for a recordkeeping system that documents the monitoring of the CCPs. Moreover, the records from such monitoring must contain the actual values and observations obtained during monitoring. However, your firm's chart recorder for the backed crab cooler did not document the correct day that the actual readings were made.

   For example, the recorder chart was misaligned so the recorded temperature readings indicating a production date of Friday 8/23/2004 at midnight through Saturday 8/24/2004 at noon were actually the readings for Monday 8/23/2004 through Tuesday 8/24/2004 at the corresponding times. Because of the misalignment, the chart recorder did not list the correct day of the week.

7. Pursuant to 21 CFR §123.8(a), your firm must verify that your firm's HACCP plan is adequate to control food safety hazards that are reasonably likely to occur. However, your firm did not verify the adequacy of the monitoring of the CCPs for all of the Seafood HACCP records maintained by the firm.

   For example, it appears that your firm's chart recorder that monitors the CCPs of the cooker is not reviewed by an individual that is trained in Seafood HACCP because the chart recorder documents are not signed or dated. In addition, the Backed Crab/Whole Cooked Crab Cooler recording charts and the Cooler Logs dated 8/16/2004 are not signed or dated. Therefore, the documentation that the values are within the CL and the appropriate corrective actions are not verified.

8. Pursuant to 21 CFR §123.8(a)(2)(ii), your firm must verify that your firm's HACCP plan is adequate to control food safety hazards that are reasonably likely to occur and that the plan is being implemented effectively by ongoing verification activities including the calibration of process-monitoring instruments. However, your firm did not calibrate the dial and continuous monitoring equipment used for monitoring temperatures of the cooking process and the recording thermometer used for monitoring the backed crab cooler listed as CCPs in your HACCP plan.

   Your firm does not have a mercury-in-glass thermometer installed in the retort cooker; therefore, there is no calibration reference to use to compare with the temperature readings of the dial and the continuous monitoring equipment, to determine if the temperature readings for the cooking process are accurate. The mercury-in-glass thermometer should be calibrated at the cooking temperature against a National Institute of Standards and Technology (NIST) traceable thermometer for accuracy once a year in order to be used as a calibration reference. In addition, all temperature gauges used in the processing of the product must be calibrated to ensure that the temperatures are accurate and correct.

9. Pursuant to 21 CFR §123.8(d), your firm must document in a record the calibration of process-monitoring instruments in accordance with 21 CFR §123.8(a)(2)(ii). However, your firm has not documented the calibration of the continuous monitoring recorder for the retort cooker, the dial thermometer for the retort cooker, and the recording thermometer for the backed crab cooler. Therefore, no documentation exists to ensure that the process-monitoring instruments are properly calibrated when used to monitor the manufacturing process. The accuracy of these instruments determines if the product is processed to eliminate the food safety hazard of pathogen growth that is identified in your HACCP plan.

We may take further action if you do not promptly correct these violations. For instance, we may initiate regulatory action without further notice. Such actions may include the initiation of a seizure action against your products and/or an action to enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as your HACCP plans, copies of all related temperature monitoring records and corrective actions, or other useful information that would assist us in evaluating

your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Carolyn A. Pinney, Compliance Officer, at the above letterhead address. If you have any questions regarding any issue in the letter, please contact Carolyn A. Pinney at (214) 253-5312.

Sincerely,

Michael A. Chappell
Dallas District Director

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